

## REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-13 and 24-26 have been examined. Claims 14-23 were withdrawn from consideration by the Examiner. Applicants acknowledge the Examiner's indication that claims 25-26 are allowable. Upon allowance of elected product claim 24, rejoinder of method claims 18-23 depending therefrom is requested. Moreover, Applicants urge rejoinder of claims 14-17 because all of the pending claims related to a single general inventive concept.

Applicants thank the Examiner for the courtesy extended by her in granting and participating in the interview of March 10, 2005. The Interview Summary is an accurate statement of what was discussed. Pursuant to a suggestion made by the Examiner during the interview, the subject matter of claims 1, 14, 18 and 24 is clarified to specify that vaccination in accordance with claims 1-24 does not involve infection by whole virus particles; support for the negative limitation would be implicitly understood by a person skilled in the art from Applicants' specification. It is noted that this limitation does not exclude the possibility that the antigenic peptide is derived from a virus (see page 14, lines 5-10, and page 15, lines 18-26, of the specification) or that the vector contains one or more virus-derived sequences (see the viral promoter described on page 15, line 33, of the specification). Applicants emphasize that the amendment is being made for clarity and is not required by the prior art.

New claims 27-34 and 46-47 are supported by page 17, lines 7-20, of the specification. They are directed to formulations in which the vector is in naked form or encapsulated. New claims 35-45 are specific embodiments of the invention which find support in claims 2-12 as originally filed.

Claims 1-9, 11-13 and 24 were rejected under Section 103(a) as allegedly being unpatentable over Rhodes (US 5,508,310) in view of Herrmann et al. (US 5,620,896). Applicants traverse.

The evidence of record discloses that tucaresol (an example of the Schiff base forming compounds recited in claim 1) is an adjuvant for conventional protein vaccines.

At issue is whether the prior art demonstrates that one of ordinary skill in the art would have been motivated to make the combination/modification proposed by the Examiner and a reasonable expectation of success. Applicants submit that the claimed invention is not *prima facie* obvious because neither motivation nor reasonable expectation of success is shown by the evidence of record: the different mechanisms and objectives of protein vaccines and DNA vaccines do not support the use of a Schiff base forming compound as an adjuvant for DNA vaccines based on its use as an adjuvant for protein vaccines. In Example 1 (pages 21-22 of the specification), adjuvants like LPS and CFA that enhance the T-cell response to peptide (Fig. 1) fail to enhance the T-cell response to DNA vaccination (Fig. 2). But the family of Schiff base forming compounds as exemplified by tucaresol was shown in Examples 2 to 8 (pages 22-28 of the specification) to enhance the immune response to DNA vaccination. Furthermore, none of the cited references teaches or suggests that tucaresol would "enhance both humoral and cellular immune responses initiated by the antigenic peptide" in the context of DNA vaccination as required by claims 1-24. To aid in the Examiner's reconsideration of Applicants' arguments, Dr. Rhodes' Declaration should also be considered.

Withdrawal of the Section 103 rejection is requested because the invention would not have been obvious to a person of ordinary skill in the art at the time it was made.

Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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